510(k) Summary
Osbone® DENTAL

JAN 1 2 2011

1. SUBMITTER/510(K) HOLDER

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Date Prepared: January 6, 2011

2. DEVICE NAME

Trade Name:	Osbone® DENTAL
Common Name:	Synthetic bone void filler
Classification Name:	Bone grafting material, synthetic

3. PREDICATE DEVICES

- BIO-OSS – Ceramic Pure Natural Hydroxyapatite (Geistlich-Pharma, K873763)
- Endobon (BIOMET, Inc., K980679)
- OsteoGraf/D (DentSply, K072056)

4. DEVICE DESCRIPTION

Osbone® DENTAL is an open-cellular, synthetic bioceramic for bone regeneration. It is comprised of a pure phase hydroxyapatite with an open sintering structure resulting in a biocompatible, bioactive and osteoconductive biomaterial. Osbone® DENTAL morsels are open-cellular highly porous morsels, ranging from 150-8000 µm for filling bone defects in dental procedures. While Osbone® DENTAL can be manufactured with a granule size of up to 8000 µm, curasan will only market granule sizes of 0.25-2.0 mm, which is within the size range of the predicate devices. The high porosity helps to accelerate ingrowth of bone.

5. INDICATIONS FOR USE

Osbone® DENTAL is intended for the filling and reconstruction of multi-walled bone defects, e.g.:

- Defects after removal of bone cysts
- Augmentation of the atrophied alveolar ridge
- Sinus lift and sinus floor elevation (subantral augmentation)
- Filling of alveolar defects following tooth extraction for alveolar ridge preservation
- Filling of extraction defects to create an implant bed
- Filling of two- or multi-walled infrabony pockets, and bi- and trifurcation defects
- Support function for a membrane in controlled tissue regeneration (CTR)
- Defects after surgical removal of retained teeth or corrective osteotomies
- Other multi-walled bone defects of the alveolar processes.

6. PRINCIPLES OF OPERATION

The principles of operation for the proposed Osbone® DENTAL are identical to the predicate devices. The morsel size is selected based on the size of the defect to be filled. If desired, the morsels may be mixed with premorselized autologous bone. The bone void filler is then applied to the prepared graft bed. The porous structure of the material makes it possible for the bone cells to grow into the matrix.

7. TECHNOLOGICAL CHARACTERISTICS

Both the proposed Osbone® DENTAL and the predicate devices are supplied in granular form. The size and porosity of the Osbone® DENTAL granules (morsels) that curasan intends to market are within the range of the size and porosity of the predicate devices.

Osbone® DENTAL is similar in material composition to the predicate devices Bio-Oss, Endobon and OsteoGraf/D. Both the proposed and predicate devices are composed of hydroxyapatite. The proposed Osbone® DENTAL and the predicate DentSply devices are chemically synthesized. The Bio-Oss and Endobon predicates are prepared from bovine bone.

The proposed Osbone® DENTAL and the predicate devices all undergo a minor amount of resorption, like any material implanted in the body. Degradation and resorption in the context of bone void fillers means that the released ions are

phagocytosed or metabolized while the nascent space becomes filled by bone. As compared to bone void fillers composed of β-TCP, the degree of resorption is negligible for bone void fillers made from hydroxyapatite due to the extremely slow resorption kinetics of high-temperature sintered hydroxyapatite. Therefore, while the term used to describe the extent of resorption for the proposed and predicate devices may be different, curasan considers that the resorption characteristics of the proposed and predicate devices are essentially identical.

8. NON-CLINICAL TESTING

Osbone® DENTAL is chemically synthesized to form a hydroxyapatite open-cellular bioceramic. Osbone® DENTAL complies with the following standards:

- ASTM F1185-03, "Specification for Composition of Hydroxyapatite for Surgical Implants"
- ISO 13779-1, "Implants for surgery: Hydroxyapatite Part 1: Ceramic hydroxyapatite."

The material was analyzed to obtain the information specified in FDA's "Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Dental Bone Grafting Material Devices" (April 28, 2005).

9. CLINICAL TESTING

No clinical testing was submitted in support of this 510(k) premarket notification.

10. CONCLUSIONS

Osbone® DENTAL shares the same indications for use, principles of operation and technological characteristics as the predicate devices BIO-OSS – Ceramic Hydroxyapatite (subject of K873763), Endobon (subject of K980679) and OsteoGraf/D (subject of K072056). Differences between the proposed and predicate devices are limited to minor difference in granule size and porosity that do not impact the safety and efficacy of the device.

curasan believes that the materials characterization data compiled for Osbone® DENTAL, along with the biocompatibility information and the history of safe clinical use for hydroxyapatite products supports the safety and effectiveness of the proposed Osbone® DENTAL for its intended use as a dental bone void filler. Therefore, curasan AG believes that the proposed Osbone® DENTAL dental bone void filler is substantially equivalent to the Bio-Oss, Endobon, and OsteoGraf/D devices.

COMPARISON TABLE FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE

	Osbone® DENTAL	**Geistlich-Pharma Bio-Oss**	**BIOMET, Inc. Endobon**	**DentSply OsteoGraf/D**
Regulatory Status	Proposed	K873763	K980679	K072056
Intended Use	Osbone® DENTAL is intended for the filling and reconstruction of multi-walled bone defects, e.g.: • Defects after removal of bone cysts • Augmentation of the atrophied alveolar ridge • Sinus lift and sinus floor elevation (subantral augmentation) • Filling of alveolar defects following tooth extraction for alveolar ridge preservation • Filling of extraction defects to create an implant bed • Filling of two- or multi-walled infrabony pockets, and bi- and trifurcation defects • Support function for a membrane in controlled tissue regeneration (CTR) • Defects after surgical removal of retained teeth or corrective osteotomies • Other multi-walled bone defects of the alveolar processes	Filling of bone defects and bone augmentation, e.g.: • Augmentation/reconstruction of alveolar ridges • Filling of extraction sockets • Implantology: preparation of implant sites, filling of bone dehiscences, and sinus floor augmentations • Periodontology: filling of bone defects, support of the membrane during guided tissue regeneration (GTR)	Used in the following dental and/or oral surgical procedures: • Alveolar ridge augmentation/reconstruction • Filling of resection defects in benign bone tumor, bone cysts, or other defects in the alveolar ridge or wall • Filling of periodontal bone pockets in the jaw (granules I) • Filling bone defects after apicetomy • Filling alveoli after tooth extraction	Treatment of intrabony periodontal defects, augmentation of bony defects in the alveolar ridge, and filling of extraction sites.
Performance	Osteoconductive	Osteoconductive	Osteoconductive	Information not available
Source	Synthetic	Bovine bone	"Bovinous bone"	Synthetic
Composition	100% HA	Cancellous bone	99% HA, 1-2% CaO and $NaCaPO_4$	100% HA
Form	Granules	Granules	Granules and Blocks/Cylinders	Granules
Granule size	0.25-1.0 mm, 1.0-2.0mm	0.25-1.0 mm, 1.0-2.0 mm	0.5-1.0 mm, 1.0-2.0 mm	0.25-0.42 mm
Porosity	80±5%*	75-80%	45-85%	None
Resorption	Partially resorbable	Partially resorbable	None	"Essentially non-resorbable"
Sterility	Sterile, Non-pyrogenic Single patient use	Sterile, Non-pyrogenic Single patient use	Sterile, Single patient use	Sterile, single patient use
Biocompatibility	Established	Established	Established	Established
Mechanical characteristics	Does not impart mechanical strength to surgical site	Does not impart mechanical strength to surgical site	Information not available	Information not available

HA = Hydroxyapatite

* In granular form (after crushing) 75±5%

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Curasan AG
C/O Cynthia J. M. Nolte, PhD
Medical Device Consultants, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760

JAN 12 2011

Re: K102872
Trade/Device Name: Osbone® Dental
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: LYC
Dated: January 6, 2011
Received: January 10, 2011

Dear Dr. Nolte:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

JAN 12 2011

510(k) Number: K102872

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- Other multi-walled bone defects of the alveolar processes.

Prescription Use _X_ AND/OR Over-The-Counter Use___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K102872